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| HARNESS, DICKEY & PIERCE, P.L.C. | | | | EXAMINER |
| P.O. BOX 828 | | | | CUMBERLEDGE, JERRY L. |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|-------------------------------------|
| Office Action Summary | Application No. 10/821,229 | Applicant(s) ZIOLO ET AL. |
| | Examiner JERRY CUMBERLEDGE | Art Unit 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 November 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 47-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 47-66 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/0256/06)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47-54, 56-62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren et al. (US Pat. 5,053,036) in view Wing (US Pat. 4,790,703).

Perren et al. disclose a bone fixation apparatus comprising: a bone fixation plate (Fig. 6, ref. 21) having a fixation hole (Fig. 6, near ref. 30); a fastener shaft passing through the fixation hole (Fig. 6), the fastener shaft having a longitudinal axis (Fig. 6), the fastener shaft including a first portion (Fig. 5, near ref. 27) having an outer surface (Fig. 6), the fastener shaft including a second bone-engaging portion (Fig. 6, near ref. 32); and an annular member (Fig. 6, near ref. 30) received in the fixation hole (Fig. 6), the annular member circumferentially surrounding the first portion of the fastener shaft (Fig. 6), wherein in an unexpanded position the fastener shaft and the annular member can rotate freely about the axis of the fastener shaft and collectively seat in the fixation hole at various angles relative to the fixation plate (Fig. 6)(column 3, lines 59-68) , and wherein in the expanded position the fastener shaft and annular member are prevented from backing out of the fixation hole (Fig. 6) (column 3, lines 59-68). The annular member has a curved outer surface mating with an inner surface of the fixation hole (Fig. 6). The outer surface of the annular member and the inner surface of the fixation

hole are spherical (Fig. 6). The annular member has an expanded diameter sufficiently large to press against the fixation hole and arrest relative movement between the fixation hole and the fastener shaft in the expanded position (Fig. 60(column 3, lines 59-68). The annular member has an expanded diameter sufficiently small to allow the annular member to freely rotate relative to the fixation hole in the expanded position (Fig. 6, when not completely expanded, but only partially expanded). The fixation plate is a spinal fixation plate for securing first and second vertebral bodies relative to one another (Fig. 6). The annular member is coupled to the fastener shaft for relative articulation therewith (Fig. 6).

Perren et al. disclose a bone fixation apparatus comprising: a bone fixation plate (Fig. 6, ref. 21) having a fixation hole (Fig. 6, near ref. 30), the fixation hole having a continuously curved inner spherical surface extending proximate an upper surface of the bone fixation plate to proximate a lower surface of the bone fixation plate (Fig. 6, near ref. 30); a fastener shaft having a longitudinal axis (Fig. 6), a bone-anchoring portion (Fig. 6, near ref. 32) and an upper portion (Fig. 6, near ref. 27); and an expandable annular member (Fig. 6, ref. 30) (column 3, lines 59-68) having an outer spherical surface (Fig. 6) and an inner surface (Fig. 6), such that in the unexpanded configuration the fastener shaft and the annular member can rotate freely about the longitudinal axis of the fastener shaft and seat in the fixation hole at various angles relative to the fixation plate (Fig. 6) (column 3, lines 59-68), and in the expanded configuration the fastener shaft and annular member are prevented from backing out of the fixation hole (Fig. 6) (column 3, lines 59-68). The annular member has an expanded

diameter sufficiently large to press against the fixation hole and arrest relative movement between the fixation hole and the fastener shaft in the expanded position (Fig. 6) (column 3, lines 59-68). The annular member has an expanded diameter sufficiently small to allow the annular member to freely rotate relative to the fixation hole in the expanded position (Fig. 6, when not completely expanded, but only partially expanded). The fixation plate is a spinal fixation plate for securing first and second vertebral bodies relative to one another (Fig. 6).

Perren et al. disclose a bone fixation apparatus comprising: a bone fixation plate (Fig. 6, ref. 21) having a fixation hole (Fig. 6, near ref. 30); a fastener shaft having a longitudinal axis (Fig. 6); and an annular member (Fig. 6, ref. 30), the annular member defining an outer surface received within the fixation hole (Fig. 6) to allow orientation of the fastener shaft at various angles relative to the bone fixation plate, the annular member having an inner surface cooperating with an outer surface of the fastener shaft to radially expand the annular member from an unexpanded position to an expanded position for preventing the fastener shaft from backing out of the fixation hole (Fig. 6) (column 3, lines 59-68).

Perren et al. disclose the claimed invention except for the fastener shaft defining a first cam and the annular member defining a second cam, the cams cooperating to selectively expand the annular member in a radial direction from an unexpanded position to an expanded position. The first and second cams are configured to provide a semi-constrained mode of operation in which the fastener shaft is retained relative to the plate and the annular member is free to move within the fixation hole and a

constrained mode of operation in which the fastener shaft is retained relative to the plate and the annular member is fixed in the fixation hole. The annular member is selectively moved between the expanded and unexpanded positions by rotation of the fastener shaft relative to the annular member and independent from longitudinal translation of the fastener shaft relative to the annular member. Each of the first and second cams include three continuously curved lobes. Perren et al. do, however, disclose a mechanism that expands the annular member to prevent rotation of components relative to one another and to lock the screw within the plate (column 3, lines 59-68).

Wing discloses a mechanism utilized with a threaded fastener (abstract) that comprises a cam on a portion of the threaded fastener and a cam on an expandable member (Fig. 3) (column 5, lines 45-68)(column 6, lines 1-4). The cams comprises three lobes (Fig. 3) (column 5, lines 45-68)(column 6, lines 1-4). The cams cooperate to prevent rotation of components relative to one another (column 5, lines 45-68)(column 6, lines 1-4).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the anti-rotational mechanism of Perren et al. with the anti-rotational mechanism of Wing which comprises cams, in order to achieve the predictable result of preventing rotation of component relative to one another.

Claims 55, 63 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren et al. (US Pat. 5,053,036) in view Wing (US Pat. 4,790,703) in view of Konieczynski et al. (US Pub. 2004/0127899 A1).

Perren et al. in view Wing disclose the claimed invention except for the fastener shaft defines a circumferentially extending groove having a reduced diameter and the annular member is carried by the fastener shaft in the circumferentially extending groove.

Konieczynski et al. disclose a bone plate and fastener system comprising an expandable annular member (abstract)(paragraph 0011) and that it is beneficial to provide different configurations of the plate, screw and expandable member, including a configuration in which the expandable member is configured to nest around a groove within the fastener (paragraph 0023), in order to provide the clinician with flexibility with respect to the manner of implementation of the system (paragraph 0023).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Perren et al. in view Wing with an expandable member being configured to nest around a groove within the fastener as taught by Konieczynski et al., in order to provide the clinician with flexibility with respect to the manner of implementation of the system (paragraph 0023).

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

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